K130451

Item I

MAY 17 2013

510(k) SUMMARY

Safety and Effectiveness

1. Medical Device Establishment:

Syntermed, Inc.
Registration No. 1066019
Owner Operator I.D. 9041128
Device Regulation Number: 892.1200
Product Code: KPS
Classification Panel: Radiology
Voice: (888) 263-4446 ext 102, FAX: (714) 281-1290
Contact person: Kenneth F. Van Train
Address: Syntermed, Inc.
130 Wieuca Road
Suite 108
Atlanta, GA 30342
Email: vantrain@syntermed.com

Date Summary Prepared: February 20, 2013

2. Medical Device:

NeuroQ 3.6 – Display and Analysis program for PET Brain studies.

Classification Name – System, Tomography, Computed, Emission

3. Medical Device Equivalence:

NeuroQ™ 3.0, Reference #: K072307 and Siemens Medical Solutions USA, Inc. Scenium 3.0, Reference #:K123528.

4. Device Description:

NeuroQ™ 3.6 has been developed to aid in the assessment of human brain scans through quantification of mean pixel values lying within standardized regions of interest, and to provide quantified comparisons with brain scans derived from FDG-PET studies of defined groups having no identified neuropsychiatric disease or symptoms, i.e., asymptomatic controls (AC). The Program provides automated analysis of brain PET scans, with output that includes quantification of relative activity in 240 different brain regions, as well as measures of the magnitude and statistical significance with which activity in each region

differs from mean activity values of brain regions in the AC database. The program can also be used to compare activity in brain regions of individual scans between two studies from the same patient, between symmetric regions of interest within the brain PET study, and to perform an image fusion of the patients PET and CT data. The program can also be used to provide analysis of amyloid uptake levels in the brain. This program was developed to run in the IDL operating system environment, which can be executed on any nuclear medicine computer systems which support the IDL software platform. The program processes the studies automatically, however, user verification of output is required and manual processing capability is provided.

5. Intended Use and Potential Adverse Effect on Health:

The intended use of this program was to provide the physician with a program which would allow him to co-register and display brain PET scans and compare the patients study to a reference database. The program can be used to compare the activity in brain regions of individual scans between two studies from the same patient, between symmetric regions of interest within the brain PET study, and to perform an image fusion of the patients PET and CT data. The program can also be used to provide analysis of amyloid uptake levels in the brain. This program serves merely as a display and processing program to aid in the diagnostic interpretation of a patient's study. It was not meant to replace or eliminate the standard visual analysis of the PET brain scan. The physician should integrate all of the patients' clinical and diagnostic information, i.e. patients' history, quality control images, visual interpretation of the PET brain scan, and quantitative results, prior to making his final interpretation. This comprehensive processing technique (as with all diagnostic imaging) is not perfect, and will be associated with some false positive and false negative results. The previous validation of the program can be found in the 510(k) submission for NeuroQ™ - PET DP, Ref. 510(k) #: K041022 and NeuroQ™ 3.0 (510(k) #: K072307. The validation for modifications in version 3.6 can be found in Item H, Testing & Validation of this 510(k) and the physician should be aware of the accuracy when integrating the quantitative results for his final interpretation. Therefore, this program has no direct adverse effect on health since the results represent only a part of the information, which the physician will utilize for his final interpretation. The final responsibility for interpretation of the study lies with the physician.

6. Marketing History:

There have been other medical device programs marketed in the past which perform similar functions to those performed by the NeuroQ™ 3.6 program. Most Nuclear Medicine manufacturers have programs that can co-register SPECT/PET data and some of them have programs for comparison of the patient's data to a reference database. NeuroQ™ 3.6 provides a program which executes in the IDL operating system environment and we believe is substantially equivalent to our previous version of NeuroQ™ - PET DP K041022 and NeuroQ™ 3.0 (510(k) #: K072307 and Siemens Medical Solutions USA, Inc. Scenium 3.0, Reference #:K123528. To our knowledge there have been no safety problems with NeuroQ™ - PET DP K041022 which has been in the marketplace since June 2004, NeuroQ™ 3.0 510(k) #: K072307 which has been in the marketplace since March 14, 2008, or Siemens

Medical Solutions USA, Inc. Scenium 3.0, Reference #:K123528 which has been in the marketplace since December 20, 2012.

7. Conclusions:

The safety of this program has been determined through the various stages of software development which included the initial design, coding, debugging, testing, and validation. The effectiveness of the initial program, NeuroQ™ - PET DP and NeuroQ™ 3.0, has been established in in-house testing and clinical validation studies submitted in our previous 510(k) K041022 and 510(k) #: K072307. Specific details and results concerning the validation of the NeuroQ™ 3.6 program are listed in Item H, Testing & Validation. We contend that the method employed for the development and the final in-house validation results of this medical display software program, NeuroQ™ 3.6, have proven its safety and effectiveness. In our opinion, NeuroQ™ 3.6 program is substantially equivalent to our previous version of NeuroQ™ - PET DP and NeuroQ™ 3.0 program and Siemens Medical Solutions USA, Inc. Scenium 3.0 which have been cleared for marketing. NeuroQ™ 3.6 program is intended for the same purpose and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Syntermed, Inc.
% Mr. Kenneth F. Van Train
President
245 Owens Drive
ANAHEIM CA 92808

May 17, 2013

Re: K130451
Trade/Device Name: NeuroQ™ 3.6
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography
Regulatory Class: Class II
Product Code: KPS
Dated: February 20, 2013
Received: February 22, 2013

Dear Mr. Van Train:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k130451

Device Name: NeuroQ™ 3.6

Indications for Use:

1) assist with regional assessment of human brain scans, through automated quantification of mean pixel values lying within standardized regions of interest (S-ROI's), and

2) assist with comparisons of the activity in brain regions of individual scans relative to normal activity values found for brain regions in FDG-PET scans, through quantitative and statistical comparisons of S-ROI's.

3) assist with comparisons of activity in brain regions of individual scans between two studies from the same patient, between symmetric regions of interest within the brain PET study, and to perform an image fusion of the patients PET and CT data

4) NeuroQ 3.6 provides added functionality to provide analysis of amyloid uptake levels in brain regions.

The product is intended for use by trained nuclear technicians and nuclear medicine physicians. The clinician remains ultimately responsible for the final interpretation and diagnosis based on standard practices and visual interpretation of all SPECT and PET data.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130451